

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): O'Leary et al.	
Serial No.: 10/759,099	Group Art Unit: 1641
Filed: January 20, 2004	Examiner:
Title: Immunoliposome-Nucleic Acid Amplification (ILNAA) Assay	
Attorney Docket No.: AFIP 03-16 01	

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

- ☒ under 37 CFR 1.97(b), or
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:
☐ Certification under 37 CFR 1.97(e), or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:
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☐ a petition under 37 CFR 1.97(d)(2)(ii), and
☐ a \$130.00 petition fee set forth in 37 CFR 1.17(i)(1).
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☒ Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

Neither this statement nor the listing of these documents on the accompanying form PTO-1449 should be considered as an admission by Applicant(s) that these materials are prior art as to Applicant(s). In addition, this statement should not be construed as a representation that no better disclosures exist.

Entry of the Information Disclosure Statement and the accompanying Form PTO-1449 are respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "M. Cahn", is written over a horizontal line.

Maurice U. Cahn, Esq.

Reg. No. 30,454

CAHN & SAMUELS, LLP

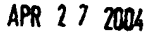
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April 27, 2004



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**INFORMATION DISCLOSURE
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(use as many sheets as necessary)

Sheet

1

of

6

Complete if Known

Application Number

10/759,099

Filing Date

January 20, 2004

First Named Inventor

O'Leary et al.

Art Unit

1641

Examiner Name

Attorney Docket Number

AFIP 03-16 01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	A	US-4,708,933	11-24-1987	HUANG, LEAF et al.	
	B	US-4,957,735	09-18-1990	HUANG, LEAF	
	C	US-5,227,170	07-13-1993	SULLIVAN, Sean	
	D	US-5,389,523	02-14-1995	PLANT, Anne L. et al.	
	E	US-5,494,803	01-27-1996	CARBONELL, RUBEN G. et al.	
	F	US-5,604,099	02-18-1997	ERLICH, HENRY A. et al.	
	G	US-5,656,493	08-12-1997	MULLIS, Kary B. et al.	
	H	US-5,665,539	09-09-1997	SANO, Takeshi et al.	
	I	US-5,716,784	02-10-1998	DI CESARE, Joseph L.	
	J	US-5,776,487	07-07-1998	MAXFIELD WILSON, Nancy et la.	
	K	US-5,858,665	01-12-1999	HEPP, Jozef et al.	
	L	US-5,922,553	07-13-1999	EBERWINE, James et al.	
	M	US-6,013,442	01-11-2000	KOLESAR, Jill M. et al.	
	N	US-6,261,771 B1	07-17-2001	BOHANNON, Robert C.	
	O	US-6,268,148 B1	07-31-2001	BARANY, Francis et al.	
	P	US-6,326,147 B1	12-04-2001	OLDHAM, Mark F. et al.	
	Q	US-6,461,817 B1	10-08-2002	ALLAND, David et al.	
	R	US-20030104506 A1	06-05-2003	DURST, Richard A. et al.	
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FOREIGN PATENT DOCUMENTS

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³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of

the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/759,099	
			Filing Date	January 20, 2004	
			First Named Inventor	O'Leary et al.	
			Group Art Unit	1641	
			Examiner Name		
Sheet	2	of	6	Attorney Docket Number	AFIP 03-16 01

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓	AA	ALFONTA, LITAL et al., "Liposomes Labeled with Biotin and Horseradish Peroxidase: A Probe for the Enhanced Application of Antigen-Antibody or Oligonucleotide-DNA Sensing Processes by the Preprecipitation of an Insoluble Product on Electrodes", Analytical Chemistry, January 1, 2001, Vol 73, No.1, pgs. 91-102.	
✓	BB	BAILEY, AUSTIN L. et al., "Efficient Encapsulation of DNA Plasmids in Small Neutral Liposomes Induced by Ethanol and Calcium", Biochimica et Biophysica Acta, 2000, Vol. 1468, pgs. 239-252.	
✓	CC	BRIDGES, MICHAEL AL. et al., "Fluorometric Determination of Nanogram Quantities of Protein in Small Samples: Application to Calcium-transport Adenosine Triphosphatase", Clin. Chim Acta 157, pgs. 73-79.	
✓	DD	CHAURAND PIERRE, et al., "Direct Profiling of Proteins in Biological Tissue Sections by MALDI Mass Spectrometry", Analytical Chemistry, December 1, 1999, Vol. 71, No. 23, pgs. 5263-5270.	
✓	EE	CHENG, SIEW BANG et al., "Development of a Multichannel Microfluidic Analysis System Employing Affinity Capillary Electrophoresis for Immunoassay", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1472-1479.	
✓	FF	CROWTHER, JOHN R., "ELISA, Theory and Practice" Meth. Mol. Biol., Vol. 42, Humana Press, Totowa, NJ., pgs. 35-62.	
✓	GG	DENY, YUZHONG et al., "Chip-based Quantitative Capillary Electrophoresis/mass Spectrometry Determination of Drugs in Human Plasma", Analytical Chemistry Vol. 73, pgs. 1432-1439.	
✓	HH	DEO, SAPNA K., et al., "An Immunoassay for Leu-enkephalin Based on a C-terminal Aequorin-peptide fusion", Analytical Chemistry, Vol. 73, pgs. 1903-1908.	
✓	II	DOUCETTE, ALAN et al., "Protein Concentration and Enzyme Digestion on Microbeads of MALDI-TOF Peptide Mass Mapping of Proteins in Dilute Solutions", Analytical Chemistry, July 15, 2000, Vol. 72, No. 1, pgs. 3355-3362.	
✓	JJ	DOYLE, J. M., et al., "Electrochemical Sensors in Immunological Analysis", Plenum Press, New York, NY, pgs. 87-102.	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓	KK	EGELHOFFER, V., Improvements protein identification by MALDI-TOF-MS Peptide mapping", Analytical Chemistry, July 1, 2000, Vol. 72, No. 13, pgs. 2741-2750.	
✓	LL	FELTUS, AGATHA et al., "Detection of Biotin in Individual Sea Urchin Oocytes Using a Bioluminescence Binding Assay", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1403-1407.	
✓	MM	FRALEY, ROBERT et al., "Introduction of Liposome-encapsulated SV40 DNA into Cells", The Journal of Biological Chemistry, November 10, 1980, Vol. 255, No. 21, pgs. 10431-10453.	
✓	NN	FRY, DAVID W., et al., "Rapid Separation of Low Molecular Weight Solutes from Liposomes Without Dilution", Academic Press Inc., 1978, pgs. 809-815.	
	OO	GOMORI, G., "A Modification of the Colorimetric Phosphorus Determination for Use with the Photoelectric Colorimeter", The Journal of Laboratory and Clinical Medicine, pgs. 955-960.	
	PP	HEATH, T.D., et al., "Covalent Attachment of Immunoglobulins to Liposomes Via Glycosphingolipids", Biochimica et Biophysica Acta, 1981, Vol. 640, pgs. 66-81.	
	QQ	HOPE, M. J., et al., "Production of Large Unilamellar Vesicles by a Rapid Extrusion Procedure. Characterization of Size Distribution, Trapped Volume and Ability to Maintain a Membrane Potential", Biochimica et Biophysica Acta, 1985, Vol. 812, pgs. 55-65.	
	RR	HUANG, CHING-HSIEN, "Studies of Phosphatidylcholine Vesicles. Formation and Physical Characteristics", Biochemistry, January 1969, Vol. 8, No. 1, pgs. 344-347.	
	SS	JONES, VIVIAN W. et al., "Microminiaturized Immunoassays Using Atomic Force Microscopy and Compositionally Patterned Antigen Arrays", Analytical Chemistry, April 1, 1998, Vol. 70, No. 7, pgs. 1233-1241.	
	TT	KUNG, VIOLA T. et al., "Synthesis of Carboxyacyl Derivatives of Phosphatidylethanolamine and Use as an Efficient Method for Conjugation of Protein to Liposomes", Biochimica et Biophysica Acta, 1986, Vol. 862, pgs. 435-439.	
	UU	LOYTER, A. et al., "Fusion-Mediated Injection of SV40-DNA. Introduction of SV40-DNA into Tissue Culture Cells by the Use of DNA-Loaded Reconstituted Sendai Virus Envelopes", Experimental Cell Research, 1983, 143, pgs. 415-425.	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
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	VV	MARTIN, FRANCIS J. et al., "Covalent Attachment of Proteins to Liposomes" in "Liposomes: a Practical Approach" (New, R.R.C., ed.) Oxford University Press, New York, NY, pgs. 163-182.	
	WW	MASON, J. T. et al., "Hydrodynamic Analysis of Egg Phosphatidylcholine Vesicles", Annals of the New York Academy of Sciences, June 19, 1978, Vol. 308, pgs. 29-49.	
	XX	MONROE, D., "Immunoassay Technology" (pal. S.B., ed.) Walter de Gruyter Co. Berlin, NY, pgs. 167-187.	
	YY	NAM, JWA-MIN et al., "Nanoparticle-Based Bio-Bar Codes for the Ultrasensitive Detection of Proteins", Science, September 26, 2003, Vol. 301, pgs. 1884-1886.	
	ZZ	NIEMEYER, CHRISTOF M. et al., "Fluorometric Polymerase Chain Reaction (PCR) Enzyme-Linked Immunosorbent Assay for Quantification of Immuno-PCR Products in Microplates", Analytical Biochemistry, 1997, Vol. 246, pgs. 140-145.	
	AAA	NIEMEYER, CHRISTOF M. et al., "Self-Assembly of DNA-Streptavidin Nanostructures and Their Use as Reagents in Immuno-PCR", October 1999, Vol. 27, No. 23, pgs. 4553-4561.	
	BBB	NEW, R. R. C., "Characterization of Liposomes" in "Liposomes: A Practical Approach, Practical Approach", (New, R.R.C., ed.) Oxford University Press, New York, NY, 1990, pgs. 105-161.	
	CCC	O'LEARY, TIMOTHY J. et al., "Use of Semiquantitative PCR to Assess Onset and Treatment of Pneumocystis Carinii Infection in Rat Model", Journal of Clinical Microbiology, March 1995, Vol. 33, No. 3, pgs. 718-724.	
	DDD	PAYNE, NICHOLAS I. Et al., "Characterization of Proliposomes", Journal of Pharmaceutical Sciences, April 1986, Vol. 75, No. 4, pgs. 330-333.	
	EEE	QIN, QIU-PING et al., "Development of Highly Fluorescent Detection Reagents for the Construction of Ultrasensitive Immunoassays", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1521-1529.	
	FFF	REID, ANN H., "Polymerase Chain Reaction" in "Advanced Laboratory Methods in Histology and Pathology", (mikel, U, ed.) American Registry of Pathology Publications Washington, DC, pgs. 77-110.	

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	GGG	RUZICKA, VIKTOR et al., "Immuno-PCR with a Commercially Available Avidin System", Science, April 30, 1993, Vol. 260, pgs. 698-699.	
	HHH	SANO, TAKESHI et al., "Immuno-PCR: Very Sensitive Antigen Detection by Means of Specific Antibody-DNA Conjugates", Science, October 2, 1992, Vol. 258, pgs. 120-122.	
	III	SHENG, ZONG-MEI et al., "Rapid Screening for KIT Mutations by Capillary Electrophoresis", Clinical Chemistry, 2001, Vol. 47, No. 7, pgs. 1325-1326.	
	JJJ	SINGH, ANUP K. et al., "Gangliosides as Receptors for Biological Toxins: Development of Sensitive Fluoroimmunoassays Using Ganglioside-Bearing Liposomes", Analytical Chemistry, December 15, 2000, Vol. 72, No. 24, pgs. 6019-6024.	
	KKK	SMITH, IAN C. P., et al., "Phosphorus-31 NMR of Phospholipids in Membranes", Academic Press, Inc. 1984, pgs. 447-460.	
	LLL	SZOKA, JR., FRANCIS et al., "Procedure for Preparation of Liposomes with Large Internal Aqueous Space and High Capture by Reverse-phase Evaporation", Pro.Natl. Acad. Sci., September 1978, Vol. 75, No. 9, pgs. 4194-4198.	
	MMM	SZOKA, JR., FRANCIS et al., "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)", Ann. Rev. Biophys. Bioeng., 1980, Vol. 9, pgs. 467-508.	
	NNN	TANABE, TETSUYA et al., "Fluorescent Cyclodextrin Immobilized on a Cellulose Membrane as a Chemosensor System for Detecting Molecules, Analytical Chemistry, April 15, 2001, Vol. 73, No. 8, pgs. 1877-1880.	
	OOO	WANG, JOSEPH et al., "Capillary Electrophoresis Microchips for Separation and Detection of Organophosphate Nerve Agents", Analytical Chemistry, April 15, 2001, Vol. 73, No. 8, pgs. 1804-1808.	
	PPP	WONG, W. M. et al., "Genomic Sequence of a Sprague-Dawley rat β -globin gene", Nucleic Acids Research, 1988, Vol. 16, No. 5, pg. 2342-2348.	
	QQQ	WU, H. C. et al., "Detection of Clostridium Botulinum Neurotoxin in Type A Using Immuno-PCR", Letters in Applied Microbiology, 2001, Vol. 31, pgs. 321-325.	

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